MAR 7 2006

510(k) Summary

Trade Name: **Provisional Inlay/Onlay Kit**

Sponsor: DMG USA, Inc.
414 South State Street
Dover, DE 19901
Registration # not yet assigned
Owner/Operator No. 9005969

Device Generic Name: Provisional Inlay/Onlay Kit

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

Predicate Devices:
The proposed Inlay/Onlay kit materials are substantially equivalent to several currently marketed dental restorative materials including the following:

Table J.1: Substantial Equivalence - Provisional Inlay/Onlay

Product Name	510(k) #	Manufacturer
Systemp.C&B Plus	K042820	Ivoclar Vivadent, Inc.
Temphase	K020092	Kerr Dental
Fermit N Lightcuring Temporary Filling Material	K934978	Ivoclar North America, Inc.
Clip	K926418	Voco GmbH
Tempit	K931084	Centrix, Inc.
First Fill R.C.S.	K011748	Jeneric/ Pentron, Inc.

The FitInspector material is substantially equivalent to the following impression material:

Table J. 2: Substantial Equivalence - FitInspector

Product Name	510(k) #	Manufacturer
Fit Checker II	K032289	GC America, Inc.

Product Description/Indications for Use:

The Provisional Inlay and Onlay materials are light-curing composites for:

- temporary care of inlay and onlay preparations
- temporary obturation of implant screw access canals
- relining material for prefabricated crowns

- temporary (light cured) cement
- individualization of splints
- forming aids for matrices
- bite registration

FitInspector is an addition-curing silicone for:

- control of precision of fit, marginal adaption and marginal gaps of:
- inlays / onlays
- crowns and bridges
- cast metal cores, crowns
- metal denture bases
- provisional cement for inlays, onlays, crowns and bridges

Safety and Performance:
This submission is an Abbreviated 510(k) as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), DMG-USA has provided information to demonstrate conformity with FDA's guidance document entitled ***Guidance for Industry and FDA Staff: Dental Composites - Premarket Notification*** (November 1998).

Conclusion:
Based on the indications for use, technological characteristics, and comparison to the predicate device, the Provisional Inlay/Onlay Kit has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 7 2006

DMG USA, Incorporated
C/O Ms. Pamela Papineau
Regulatory Affairs Consultant
Delphi Medical Device Consulting
5 Whitcomb Avenue
Ayer, Massachusetts 01432

Re: K052800
Trade/Device Name: Provisional Inlay/Onlay Kit
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Codes: EBG and ELW
Dated: February 28, 2006
Received: March 03, 2006

Dear Ms. Papineau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K052800

Device Name: Provisional Inlay/Onlay Kit

Indications for Use:

The provisional inlay and onlay materials are light-curing composites for:

- temporary care of inlay and onlay preparations
- temporary obturation of implant screw access canals
- relining material for prefabricated crowns
- temporary (light cured) cement
- individualization of splints
- forming aids for matrices
- bite registration

FitInspector is an addition-curing silicone for:

- control of precision of fit, marginal adaption and marginal gaps of:
  - inlays / onlays;
  - crowns and bridges;
  - cast metal cores, crowns;
  - metal denture bases; and
- provisional cement for inlays, onlays, crowns and bridges

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-the -Counter Use ____ (21 CFR 807 Subpart D)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K052800